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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/405,046	09/27/1999	THOMAS MEADE	A-58634-6/RF	9059
32940	7590	08/09/2006		
DORSEY & WHITNEY LLP 555 CALIFORNIA STREET, SUITE 1000 SUITE 1000 SAN FRANCISCO, CA 94104			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/405,046

Applicant(s)

MEADE ET AL.

Examiner

D. L. Jones

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/18/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,30,32,41,42,45,48,49 and 58-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,30,32,41,42,45,48,49 and 58-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 5/18/06 wherein claims 1-21, 23-29, 31,33-40, 43, 44, 46, 47, and 50-57 are canceled and claims 22, 30, and 42 are amended.

Note: Claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 are pending.

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/18/06 has been entered.

RESPONSE TO APPLICANT'S ARGUMENTS/AMENDMENT

3. The Applicant's arguments and/or amendment filed 5/18/06 to the rejection of claims 22, 30, 32, 41, 45, 48, 49, and 58-66 made by the Examiner under 35 USC 103 and/or 112 have been fully considered and deemed non-persuasive for reasons of record in the office action mailed 4/22/05 and those set forth below.

112 First Paragraph Rejections

I. The rejection of claims 61, 62, 65, and 66 under 35 USC 112, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 4/22/05 and those set forth below.

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II. The rejection of claims 22, 30, 32, 41, 42, 45, 48, 49, and 58-66 under 35 USC, first paragraph, as failing to comply with the written description requirement is MAINTAINED for reasons of record in the office action mailed 4/22/05 and those set forth below.

Applicant's assertions may be summarized as follows. (a) There is no requirement of providing a precise definition such as by sequence in order to meet the requirement of the written description requirement. (b) The instant claims meet the written description requirement because they disclose both structure and function and a correlation between structure and function. (c)

Applicant's arguments have been considered, but are not persuasive for reasons of record in the office action mailed 4/22/05. While it is noted that Applicant is attempting to use properties to distinguish their claims over the prior art, it should be noted that (1) for product claims, patentability is dependent upon the components present in the product. For example, for claim 33 (a product claim), the components present in the agent are a chelator, gadolinium metal, linker, and peptide. What happens upon cleavage of the peptide with a caspase and the fact that T1 changes as a result of cleavage with caspase does not carry patentability weight. In other words, when the prior art discloses the same components of the agent as claimed by Applicant, then, the prior art reads on the instant invention. (2) A product is not separable from its properties. Thus, when the art discloses Applicant's product, the properties as claimed by Applicant (i.e., a change in T1 as a result of cleavage of a peptide with caspase) are

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inherent properties of the composition. Hence, the reference does not have to specifically state how and why T1 changed.

(3) While caspase cleavable peptides are known in the art, Applicant cannot randomly select peptides of the prior art and insert them into the instant invention. There is no indication in the instant disclosure that those specific peptides are compatible with the instant invention. What made Applicant select some specific caspase cleavable peptides and not others? But more importantly, based on the disclosure of the instant application, the particular, species randomly selected and incorporated into the claims do not appear to be envisioned by the instant invention. As a result, what the reader extracts from the claims/specification is a desire, plan, or first steps for obtaining a desired result. Based on the written description requirement, an Inventor must be able to describe the item to be patented with such clarity that the reader is assured that the Inventor actually has possession and knowledge of the unique composition and/or method for which patent protection is sought.

(4) Furthermore, page 22, lines 19 and 20 disclose caspases 3, 5, and 8; however, claim 59, for example, claims caspase 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10. Hence, what is set forth in the claims is not consistent with the disclosure.

112 Second Paragraph Rejections

The rejection of claims 30, 32, 41, 48, 63, and 64 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the

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subject matter which Applicant regards as the invention is MAINTAINED for reasons of record in the office action mailed 4/22/05 and those set forth below.

Applicant asserts that 'without admitting the propriety of the rejection and reserving the right too pursue the broader claim in continuing applications, claim 30 and dependent claims 32, 41, 48, and 63', the phrase 'under conditions whereby said peptide is cleaved with caspase results in the claims being definite.

Applicant's arguments are not persuasive. The main issue here is the phrase 'a method comprising...or a salt thereof'. In particular, this phrase does not set forth what type of method is being claimed. Is it a method of imaging, a method of treating a condition, or some other method? Also, the method steps only require that the agent be administered and an image generated. The phrase 'under conditions whereby said peptide is cleaved' is irrelevant identifying the type of method that is being claimed. The phrase does not allow one to determine if the method is for treating a condition, generating an image, or some other method. Neither does it identify the condition whereby the peptide is cleaved or require a method step that actually requires cleavage of the peptide. Thus, the claims remain ambiguous.

103 Rejection

I. The rejection of claim 22 under 35 USC 103(a) as being unpatentable over Gries et al (US Patent No. 5,648,063) is MAINTAINED for reasons of record in the office action mailed 4/22/05 and those set forth below.

Applicant asserts that (a) Gries et al does not teach 'upon cleavage of said peptide' with a caspase, the T1 of the MRI agent changes and (b) there is no suggestion or motivation in Gries et al that the invention be modified to achieve the instant invention.

Applicant's arguments are non-persuasive for the following reasons. Claim 22 is directed to a product comprising a chelator, gadolinium metal, linker, and peptide. Thus, what happens once the peptide is cleaved does not change the components of the product. In other words, for a product claim, the cleaving of the peptide and change in T1 would be considered in the patentability determination. However, for a product claim, patentability is based on the components present in the product, not the steps that the product is generated.

II. The rejection of claims 30, 32, 41, 42, 45, 48, 49, and 58-60 under 35 USC 103(a) as being unpatentable over Gries et al (US Patent No. 5,648,063) in view of Zychlinsky et al (US Patent No. 5,872,899) is MAINTAINED for reasons of record in the office action mailed 4/22/05 and those set forth below.

Applicant asserts that (a) there is no motivation or suggestion in either Gries or Zychlinsky et al to modify the invention of Gries et al and achieve the instant invention and (b) there is no expectation to success in combining Gries with Zychlinsky et al.

Applicant's arguments are non-persuasive for the following reasons. (1) The primary reference, Gries et al, discloses a product having the components as set forth in Applicant's product claims. (2) The secondary reference, Zychlinsky et al disclose

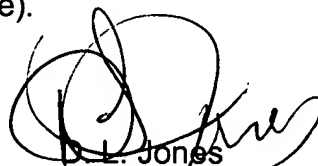
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proteins and peptides that bind to caspase (also known as interleukin-1 beta converting enzyme). (3) Since Applicant's product is rendered obvious by the prior art and it is known in the art for peptides to be bound with caspase, it is inherent that T1 would be altered.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


D. L. Jones
Primary Examiner
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August 7, 2006